

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|---|--|
| In re Application of Jardieu et al. Serial No.: To be assigned Filed: 3 December 2003 For: ANTIBODY MUTANTS | Group Art Unit: To be assigned Examiner: To be assigned CUSTOMER NO: 09157 |
| | Express Mail No. EV 351932389 US Mailed: December 3, 2003 |

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 08/975,329, filed 20 November 1997 and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

(X) not given

- given for each listed item
- given for only non-English language listed item(s) (Required)
- in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: December 3, 2003

By: Lee Tan
Lee K. Tan, Ph.D.
Reg. No. 39,447
Telephone No. (650) 225-4462

| | | | | | | | |
|---|--|--|--|---|-------|------------------------------|------------|
| FORM PTO-1449 | | | | U.S. Dept. of Commerce Patent and Trademark Office | | Atty Docket No. P1064R1C1 | Serial No. |
| LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary) | | | | Applicant Jardieu et al. | | | |
| | | | | Filing Date 03 Dec 2003 | Group | | |

U.S. PATENT DOCUMENTS

| Examiner Initials | | Document Number | Date | Name | Class | Subclass | Filing Date |
|-------------------|-----|-----------------|----------|----------------|-------|----------|-------------|
| | * 1 | 4,816,567 | 28.03.89 | Cabilly et al. | | | |
| | * 2 | 5,994,511 | 30.11.99 | Lowman et al | | | |
| | * 3 | 6,210,671 | 03.04.01 | Co, M. | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials | | Document Number | Date | Country | Class | Subclass | Translation Yes | Translation No |
|-------------------|------|-----------------|----------|---------|-------|----------|-----------------|----------------|
| | * 4 | 364,690 | 25.04.90 | EPO | | | | |
| | * 5 | 699,755 | 06.03.96 | EPO | | | | |
| | * 6 | EP 440,351 | 07.08.91 | EPO | | | | |
| | * 7 | WO 91/09967 | 11.07.91 | PCT | | | | |
| | * 8 | WO 91/16927 | 14.11.91 | PCT | | | | |
| | * 9 | WO 93/01296 | 21.01.93 | PCT | | | | |
| | * 10 | WO 95/23813 | 08.09.95 | PCT | | | | |
| | * 11 | WO 96/32478 | 17.10.96 | PCT | | | | |
| | * 12 | WO 96/36359 | 21.11.96 | PCT | | | | |
| | * 13 | WO 97/31024 | 28.08.97 | PCT | | | | |

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

| | | |
|--|-----|---|
| | *14 | Barry, J., "Immunosuppressive drugs in renal transplantation. A review of the regimens" <u>Drugs</u> 44:554-566 (1992) |
| | *15 | Carter et al., "Engineering Subtilisin BPN' for Site-Specific Proteolysis" <u>Proteins: Struct. Funct., Genet.</u> 6:240-248 (1989) |
| | *16 | Carter et al., "Humanization of an Anti-p185HER2 Antibody For Human Cancer Therapy" <u>Proc. Natl. Acad. Sci. USA</u> 89:4285-4289 (May 1992) |
| | *17 | Cavazzana-Calvo et al., "Prevention of bone marrow and cardiac graft rejection in an H-2 haplotype disparate mouse combination by an anti-LFA-1 antibody" <u>Transplantation</u> 59:1576-1582 (1995) |
| | *18 | Champe et al., "Monoclonal antibodies that block the activity of leukocyte function-associated antigen 1 recognize three discrete epitopes in the inserted domain of CD11a" <u>Journal of Biological Chemistry</u> 270:1388-1394 (1995) |
| | *19 | Chothia, C. et al., "Conformations of immunoglobulin hypervariable regions" <u>Nature</u> 342(6252):877-883 (1989) |
| | *20 | Cunningham and Wells, "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis" <u>Science</u> 244:1081-1085 (1989) |
| | *21 | Cunningham et al., "Receptor and Antibody Epitopes in Human Growth Hormone Identified by Homolog-Scanning Mutagenesis" <u>Science</u> 243:1330-1336 (1989) |
| | *22 | Dantil et al., "Use of Monoclonal Antibodies in Human Transplantation" <u>Current Opinion in Immunology</u> 3:740-747 (1991) |
| | *23 | de Fougerolles et al., "Characterization of ICAM-2 and evidence for a third counter-receptor for LFA-1" <u>Journal of Experimental Medicine</u> 174:253-267 (1991) |

| | |
|---|-----------------|
| Examiner | Date Considered |
| *Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

| | | | | |
|---|--|---|------------------------------|------------|
| FORM PTO-1449 | | U.S. Dept. of Commerce Patent and Trademark Office | Atty Docket No. P1064R1C1 | Serial No. |
| LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary) | | Applicant Jardieu et al. | | |
| | | Filing Date 03 Dec 2003 | Group | |
| OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.) | | | | |
| *24 | de Fougerolles et al., "Characterization of the function of intercellular adhesion molecule (ICAM)-3 and comparison with ICAM-1 and ICAM-2 in immune responses" <u>Journal of Experimental Medicine</u> 179:619-629 (1994) | | | |
| *25 | Dougherty et al., "The role of monocyte lymphocyte function-associated antigen 1 (LFA-1) in accessory cell function" <u>European Journal of Immunology</u> 17:943-947 (1987) | | | |
| *26 | Dustin et al., "Induction By IL 1 and Interferon- γ : Tissue Distribution, Biochemistry, and Function of a Natural Adherence Molecule (ICAM-1)" <u>The Journal of Immunology</u> 137(1):245-254 (July 1, 1986) | | | |
| *27 | Eaton et al., "Construction and characterization of an active factor VIII variant lacking the central one-third of the molecule" <u>Biochemistry</u> 25:8343-8347 (1986) | | | |
| *28 | Edwards et al., "Identification of Amino Acids in the CD11a I-domain Important for Binding of the Leukocyte Function-associated Antigen-1 (LFA-1) to Intercellular Adhesion Molecule-1 (ICAM-1)" <u>Journal of Biological Chemistry</u> 270(21):12635-12640 (May 26, 1995) | | | |
| *29 | Eigenbrot et al., "X-Ray Structures of Fragments From Binding and Nonbinding Versions of a Humanized Anti-CD18 Antibody: Structural Indications of the Key Role of V _H Residues 59 to 65" <u>Proteins: Structure, Function, and Genetics</u> 18:49-62 (1994) | | | |
| *30 | Eigenbrot et al., "X-Ray Structures of the Antigen-Binding Domains From Three Variants of Humanized Anti-p185HER2 Antibody 4D5 and Comparison With Molecular Modeling" <u>J. Mol. Biol.</u> 229:969-995 (1993) | | | |
| *31 | Ellison et al., "The nucleotide sequence of a human immunoglobulin C _y 1 gene" <u>Nucleic Acids Research</u> 10(13):4071-4079 (1982) | | | |
| *32 | Fischer et al., "Reduction of Graft Failure by a Monoclonal Antibody (Anti-LFA-1 CD11a) After HLA Nonidentical Bone Marrow Transplantation in Children with Immunodeficiencies, Osteopetrosis, and Fanconi's Anemia" <u>Blood</u> 77(2):249-256 (January 15, 1991) | | | |
| *33 | Fischer et al., "Role of the LFA-1 Molecule in Cellular Interactions Required For Antibody Production in Humans" <u>The Journal of Immunology</u> 136(9):3198-3203 (May 1, 1986) | | | |
| *34 | Gorman et al., "High efficiency DNA-mediated transformation of primate cells" <u>Science</u> 221:551-553 (1983) | | | |
| *35 | Gorman et al., "Transient Production of Proteins Using an Adenovirus Transformed Cell Line" <u>DNA Prot. Eng. Tech.</u> 2(1):3-10 (1990) | | | |
| *36 | Graham et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5" <u>J. Gen. Virol.</u> 36:59-72 (1977) | | | |
| *37 | Hawkins et al., "Selection of Phage Antibodies by Binding Affinity Mimicking Affinity Maturation" <u>J. Mol. Biol.</u> 226:889-896 (1992) | | | |
| *38 | He et al., "Effect of LFA-1 and ICAM-1 antibody treatment on murine corneal allograft survival" <u>Invest. Ophthalmol. Vis. Sci.</u> 35:3218-3225 (1994) | | | |
| *39 | Hildreth et al., "A Human Lymphocyte-associated Antigen Involved in Cell-mediated Lympholysis" <u>European Journal of Immunology</u> 13:202-208 (1983) | | | |
| *40 | Hildreth et al., "The human lymphocyte function-associated (HLFA) antigen and a related macrophage differentiation antigen (HMac-1): functional effects of subunit-specific monoclonal antibodies" <u>J. Immunol.</u> 134:3272-3280 (1985) | | | |
| *41 | Hourmant et al., "Administration of an Anti-CD11a Monoclonal Antibody in Recipients of Kidney Transplantation" <u>Transplantation</u> 58(3):377-380 (August 1994) | | | |
| *42 | Jones et al., "Replacing the Complementarity-Determining Regions in a Human Antibody with Those From a Mouse." <u>Nature</u> 321:522-525 (May 29, 1986) | | | |
| *43 | Kabat et al. <u>Sequences of Proteins of Immunological Interest</u> , U.S. Dept. of Health and Human Services, NIH, 5th edition Vol. 1:103-108, 324-331 (1991) | | | |
| Examiner | | Date Considered | | |
| *Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | |

| | | | | |
|---|---|---|------------------------------|------------|
| FORM PTO-1449 | | U.S. Dept. of Commerce Patent and Trademark Office | Atty Docket No. P1064R1C1 | Serial No. |
| LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary) | | Applicant Jardieu et al. | | |
| | | Filing Date 03 Dec 2003 | Group | |
| OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.) | | | | |
| *44 | Kelley et al., "Characterization of Humanized Anti-p185HER2 Antibody Fab Fragments Produced in Escherichia coli" <u>Protein Folding In Vivo and In Vitro</u> , Jeffrey L. Cleland, Washington, D.C.:American Chemical Society pps. 218-239 (1993) | | | |
| *45 | Krensky et al., "The Functional Significance, Distribution, and Structure of LFA-1, LFA-2, and LFA-3: Cell Surface Antigens Associated with CTL-Target Interactions" <u>The Journal of Immunology</u> 131(2):611-616 (August 1983) | | | |
| *46 | Kunkel, T., "Rapid and Efficient Site-Specific Mutagenesis Without Phenotypic Selection" <u>Proc. Natl. Acad. Sci.</u> 82:488-492 (1985) | | | |
| *47 | Kuypers and Roos, "Leukocyte Membrane Adhesion Proteins LFA-1, CR3 and p150,95: A Review of Functional and Regulatory Aspects" <u>Res. Immunol.</u> 140:461-486 (1989) | | | |
| *48 | Larson et al., "Structure and Function of Leukocyte Integrins" <u>Immunological Reviews</u> 114:181-217 (1990) | | | |
| *49 | Lo et al., "Two Leukocyte Receptors (CD11a/CD18 and CD11b/CD18) Mediate Transient Adhesion to Endothelium by Binding to Different Ligands" <u>The Journal of Immunology</u> 143(10):3325-3329 (November 15, 1989) | | | |
| *50 | Lowman et al., "Selecting High-Affinity Binding Proteins by Monovalent Phage Display" <u>Biochemistry</u> 30(45):10832-10838 (1991) | | | |
| *51 | McCabe et al., "sICAM-1 Enhances Cytokine Production Stimulated by Alloantigen" <u>Cellular Immunology</u> 150:364-375 (1993) | | | |
| *52 | McClure, H., "Nonhuman Primate Models for Human Disease" <u>Advances in Veterinary Science and Comparative Medicine</u> 28:267-304 (1984) | | | |
| *53 | Nakakura et al., "Potent and Effective Prolongation by Anti-LFA-1 Monoclonal Antibody Monotherapy of Non-Primarily Vascularized Heart Allograft Survival in Mice Without T Cell Depletion" <u>Transplantation</u> 55(2):412-417 (February 1993) | | | |
| *54 | Nishihara et al., "Potent immunosuppressive effect of anti-LFA-1 monoclonal antibody on islet allograft rejection" <u>Transplantation Proc.</u> 27:372 (1995) | | | |
| *55 | Parlevliet et al., "Monoclonal antibodies in renal transplantation: a review" <u>Transplant. Intl.</u> 5:234-246 (1992) | | | |
| *56 | Presta et al., "Humanization of an Antibody Directed Against IgE" <u>J. Immunol.</u> 151(5):2623-2632 (September 1, 1993) | | | |
| *57 | Reimann et al., "Use of human leukocyte-specific monoclonal antibodies for clinically immunophenotyping lymphocytes of rhesus monkeys" <u>Cytometry</u> 17:102-108 (1994) | | | |
| *58 | Riechmann et al., "Reshaping Human Antibodies for Therapy" <u>Nature</u> 332:323-327 (Mar 24, 1988) | | | |
| *59 | Saban et al., "Humanized Anti-IgE Monoclonal Antibody Mae25 Blocks Passive Sensitization of Rhesus Monkey Bladder In Vitro" <u>FASEB J.</u> (Abstract 3953) 8(5):A682 (March 18, 1994) | | | |
| *60 | Simmons et al., "ICAM, an adhesion ligand of LFA-1, is homologous to the neural cell adhesion molecule NCAM" <u>Nature</u> 331:624-627 (1988) | | | |
| *61 | Staunton, D.E., et al., "Primary Structure of ICAM-1 Demonstrates Interaction between Members of the Immunoglobulin and Integrin Supergene Families" <u>Cell</u> 52:925-933 (1988) | | | |
| *62 | Stoppa et al., "Anti-LFA1 Monoclonal Antibody (25.3) for Treatment of Steroid-resistant Grade III-IV Acute Graft-versus-host Disease" <u>Transplant International</u> 4:3-7 (1991) | | | |
| *63 | Talento et al., "A single administration of LFA-1 antibody confers prolonged allograft survival" <u>Transplantation</u> 55:418-422 (1993) | | | |
| Examiner | | Date Considered | | |
| *Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | |

| | | | | |
|---|---|---|------------------------------|------------|
| FORM PTO-1449 | | U.S. Dept. of Commerce Patent and Trademark Office | Atty Docket No. P1064R1C1 | Serial No. |
| LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary) | | Applicant Jardieu et al. | | |
| | | Filing Date 03 Dec 2003 | Group | |
| OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.) | | | | |
| *64 | Tanaka et al., "Prolonged inhibition of an antigen-specific IgE response in vivo by monoclonal antibody against lymphocyte function-associated antigen-1" <u>European Journal of Immunology</u> 25:1555-1558 (1995) | | | |
| *65 | Tramontano et al., "Framework residue 71 is a major determinant of the position and conformation of the second hypervariable region in the V _H domains of immunoglobulins" <u>J. Mol. Biol.</u> 215(1):175-182 (Sep 5, 1990) | | | |
| *66 | Van Dijken et al., "Evidence That Anti-LFA-1 in vivo Improves Engraftment and Survival After Allogeneic Bone Marrow Transplantation" <u>Transplantation</u> 49(5):882-886 (May 1990) | | | |
| *67 | Verhoeven et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity" <u>Science</u> 239:1534-1536 (Mar 25, 1988) | | | |
| *68 | Werther et al., "Humanization of an Anti-Lymphocyte Function-Associated Antigen (LFA)-1 Monoclonal Antibody and Reengineering of the Humanized Antibody for Binding to Rhesus LFA-1" <u>J. of Immunology</u> 157:4986-4995 (1996) | | | |
| *69 | Wognum et al., "Immunochemical Analysis of Monoclonal Antibodies to Human Erythropoietin" <u>Exp. Hematology</u> 18:228-233 (1990) | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Examiner | | Date Considered | | |
| *Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | |